UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,717	07/14/2006	Dan Gazit	30695	6234

7590 09/18/2007

Martin Moynihan
Prtsi Inc
P O Box 16446
Arlington, VA 22215

EXAMINER	
SINGH, ANOOP KUMAR	
ART UNIT	**PAPER NUMBER**
1632	

MAIL DATE	DELIVERY MODE
09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,717	GAZIT ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *87-111* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *87-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' preliminary amendments to the claims filed on 10/03/2005 has been received and entered. Claims 1-86 have been cancelled and claims 87-111 have been added. Claims 87-111 are pending in this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 87-89, 92-93, drawn to a method of regulating an activity of a SMAD protein in a cell by contacting the cell with a polypeptide encoded by a nucleic acid having a nucleotide sequence at least 70% homologous to SEQ ID NO: 1 and/or SEQ ID NO: 2 capable of modulating an expression and/or an activity of TAK1 in the cell, thereby regulating the activity of the SMAD protein in the cell.

Group II, claims 87-88, 90-93, drawn to a method of regulating an activity of a SMAD protein in a cell by contacting the cell with single-stranded or double-stranded oligonucleotide which is at least 12 nucleotides in length and is specifically hybridizable with SEQ ID NO: 1 and/or 2 capable of modulating an expression and/or an activity of TAK1 in the cell, thereby regulating the activity of the SMAD protein in the cell.

Group III, claims 94-96, 99-104, drawn to a method of regulating osteogenesis and/or bone repair in a subject in need thereof comprising contacting a cell with osteogenic potential with a polypeptide encoded by a nucleic acid capable of modulating an expression of TAK1 in the cell, wherein: (i) said cell is located in the subject; and/or (ii) said contacting is effected in-vitro, thereby generating a treated cell, and the method further comprises the step of administering said treated cell to the subject, thereby regulating osteogenesis in the subject.

Group IV, claims 94-95, 97-104, drawn to a method of regulating osteogenesis in a subject comprising contacting a cell with osteogenic potential with a single-stranded or double-stranded oligonucleotide which is at least 12 nucleotides in length and is

specifically hybridizable with SEQ ID NO: 1 and/or 2, wherein: (i) said cell is located in the subject; and/or (ii) said contacting is effected in-vitro, thereby generating a treated cell, and the method further comprises the step of administering said treated cell to the subject, thereby regulating osteogenesis in the subject.

Group V, claims 105-111, drawn to a composition comprising an isolated nucleic acid having a nucleic acid sequence at least 70% homologous to a nucleic acid sequence of a nucleic acid selected from the group consisting of SEQ ID NO: 1, SEQ ID NO: 2, an antisense strand of SEQ ID NO: 1, and an antisense strand of SEQ ID NO: 2, vector and host cell comprising the vector comprising the nucleic acid of the invention.

If claim 105-111 (group V) is elected then a further restriction in nucleotide sequence is required among SEQ ID NO: 1, SEQ ID NO: 2, an antisense strand of SEQ ID NO: 1, and an antisense strand of SEQ ID NO: 2 as each sequence has a distinct physical and chemical structure and encodes different protein, therefore, requires different search in commercial database. Applicant is required to elect one Seq ID No in said groups.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant case, claims are directed to a an agent capable of modulating an expression and/ or activity of TAK1 in the cells. Hibuya et al (EMBO J. February 1998, Vol. 17, No. 4,pages 1019-1028, see entire document, IDS) teach a method of reducing SMAD activity by transfecting a cell with a polynucleotide encoding a kinase negative from of TAK1, which is known to inhibit endogenous signaling of SMAD. The cited art teaches the same method step as claimed in the instant invention. Therefore, the instant technical feature does not contribute over prior art.

In addition, the inventions are distinct fro each from other because of the following reasons: In the instant case the inventions of groups I-V are patentably distinct, each from other because they are drawn to methods or compositions that have distinct step and use material compositions that have distinct structure, function and utility. For instance method of group I requires delivering protein to modulate the SMAD activity, while group II requires administering nucleic acid. It

is noted that protein and nucleic are structurally different and elicit pharmacological effect by different mechanism. Invention of group III requires delivery of cell treated with either polypeptide (group III) or nucleic acid (group IV) ex vivo for the regulating osteogenesis in a subject. In contrast invention of group V is directed to a composition comprising isolated nucleic acid, vector or a host cell comprising nucleic acid which could be used in drug screening. Each of these involves distinct and different method steps and composition and therefore, searching for distinct method steps and composition will not be coextensive and will require separate and independent searches in the patent and non-patent literature.

Each invention is directed to distinct goal, which comprises the use polypeptide or nucleic acid encoding polypeptide of the invention in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one

claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anoop Singh
AU 1632

/Thaian N. Ton/
Primary Examiner
Art Unit 1632